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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,903	10/27/2000	Brigitte Weston	514412-2020.1	8217

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,903	WESTON ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-26,30-32 and 34-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26,30-32 and 34-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *27 October 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 November 2003 has been entered.

2. Claims 24-26, 30-32 and 34-42 are pending.

3. The amendment filed 6 November 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: The amendment of the paragraph beginning pg 16, line 15, of the specification is new matter. There is no support in the originally filed specification for recitation of oligonucleotides being at least 16 or 20-24 nucleotides long.

Applicant is required to cancel the new matter in the reply to this Office Action.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The terminal disclaimer filed on 6 November 2003 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of 6,509,516 has been reviewed and is accepted. The terminal disclaimer has been recorded.

6. The rejection of claims 23-32 and 34-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,509,516 is withdrawn in light of the filing of a terminal disclaimer over this patent.

Claim Rejections - 35 USC § 112

7. Claims 24-26, 30-32 and 34-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the originally filed specification nor the originally filed claims appear to provide support for recitation of oligonucleotides comprising at least any 16 consecutive nucleotides of bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10, or of SEQ ID NO:1 in claims 24, 26, 30, and 34-36. Thus, such a recitation constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

8. Claims 37-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the originally filed specification nor the originally filed claims appear to provide support for recitation of probes or primers comprising any 20-24 nucleotides of bases 1-234 of SEQ ID NO:8, bases 194-416 of SEQ ID NO:10, or of SEQ ID NO:1 in claims 37-42. Thus, such a recitation constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

9. Claims 24-26, 30-32 and 34-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying elite event MS-B2 in transgenic Brassica or confirming seed purity using TAIL-PCR and primers SEQ ID NOs:4-7 and 9 or PCR using SEQ ID NOs:11-14, does not reasonably provide enablement for a method of identifying elite event MS-B2 in transgenic Brassica or confirming seed purity using PCR with any primer or using any other hybridization method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 July 2003, as applied to claims 23-26, 29-32 and 34-36. Applicant's arguments filed 6 November 2003 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to recite that the PCR probes or primers comprise at least 16 or 20-24 nucleotides from the foreign DNA, from the 5' flanking region or the 3' flanking region and that specific oligonucleoitdes of that size are exemplified in the specification (response pg 8).

This is not found persuasive because the listed primers of SEQ ID NOs:2-3 and 11-14 are all 21-23 nucleotides long; thus no oligos that are less than 21 nucleotides long or longer than 23 nucleotides are exemplified.

Applicant urges that one of skill in the art based on standard PCR protocols would use oligonucleotides that are 16 or 20-24 nucleotides long and could envision each and every probe or primer encompassed by the claims using a length-adjustable window (response pg 8-9).

This is not found persuasive because not all oligonucleotides that are 16 or 20-24 nucleotides long will function as PCR primers that specifically amplify MS-B2 event DNA, as opposed to other DNA in the Brassica genome; those that comprise repetitive sequences will bind to nucleic acids that are not the intended target. The specification does not provide guidance for which oligonucleotides to use within the full scope of the claims.

Applicant urges that the development of PCR primers is routine and predictable, given the guidance in the specifictaion and working examples in the specification, the skill of those in the art and the predictability of the art; need for some expreimentation does not outweigh this (response pg 9-10).

This is not found persuasive because the specification only provides guidance for primers of SEQ ID NOs:2-3 and 11-14, none of which are 16 or 20 nucleotides long or 24 nucleotides long or longer. The specification provides no guidance for probes within the full scope of the invention.

Twenty-base long primers comprises in bases 1-234 of SEQ ID NO:8 or bases 194-416 of SEQ ID NO:10 or to SEQ ID NO:1, or the complement thereof, would encompass approximately 12600 20-base long primers that have exact complementarity to the claimed sequences and multitudes more primers of other lengths and/or that have mismatches. Applicant has taught only 9 primers that function in the invention, and none are 20 nucleotides long. Applicant has not taught primers that encompass the full scope of the claimed invention.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling

disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicant urges that they should not be limited only to the exemplified primers and that no evidence has been provided that one of skill in the art could not use the claimed genus without undue experimentation (response pg 10).

This is not found persuasive because for the full scope of the claims to be enabled, the specification must provide guidance for oligonucleotides that are 16 or 20 nucleotides long or 24 nucleotides long. Applicant is limited to the primers for which they provide guidance, which is not necessarily just the exemplified primers; Applicant should point to portions of the specification that provide guidance for other primers.

10. Claims 24-26, 30-32 and 34-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 July 2003, as applied to claims 23-26, 29-32 and 34-36. Applicant's arguments filed 6 November 2003 have been fully considered but they are not persuasive.

Applicant urges that they need not have physical possession of each and every primer and probe encompassed by the claims, and that the structural features that distinguish the probes and primers from other nucleic acids are clearly delimited by the requirement that they be derived from SEQ ID NOs: 1, 8 or 10 (response pg 10-11).

This is not found persuasive because all primers can be used in PCR analysis; some, because, for example, they comprise repetitive sequences, will bind to nucleic acids that are not the intended target. The specification must describe those that can be used.

Applicant urges that a representative number of cDNAs falling within the genus have been disclosed (response pg 11).

This is not found persuasive because the specification does not describe 16 oligonucleotide probes and primers at all and describes no oligonucleotides that are less than 21 nucleotides long or longer than 23 nucleotides. The rejection is not directed to cDNAs.

11. Claims 24-26, 30-32 and 34-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 July 2003, as applied to claims 23-26, 29-32 and 34-36. Applicant's arguments filed 6 November 2003 have been fully considered but they are not persuasive.

Claim 24, line 5, claim 34, line 3, and claim 36, line 4 are indefinite in their recitation of "using a polymerase chain reaction" and claim 24, line 14, is indefinite in its recitation of "using PCR" in line 14. The PCR steps should be recited as active, positive steps delimiting how this use is actually practiced. It is not clear how PCR is used.

Applicant urges that claim 36 more clearly defines the steps (response pg 11).

Applicant urges that the steps of using a PCR are more clearly defined in claim 36.

This is not found persuasive because recitation of probes and primers does not define what one must do to practice the invention. The instant claims should recite the claimed PCR conditions and make clear how PCR is used.

The following rejections are new, due to amendment of the claims.

In claims 24 and 34-36, the methods should be written so that the method steps are detailed, following by a method step wherein if the PCR fragment is produced, one decides that event MS-B2 is present in the plant or if the fragment is not produced, one decides that event MS-B2 is not present in the plant. As currently written the claims make little sense, because one cannot, as in claim 24, amplifying a fragment, then identify the event if the fragment is amplified, because the fragment has already been amplified.

Claim 24, lines 6 and 10, claims 25-26, line 1, claim 30, line, line 7, claim 34, lines 4 and 7, claim 35, lines 3-4 and 7, claim 36, line 9, claim 36, lines 1 and 5, claims 38-39, line 1, and claim 40, line 5 are indefinite in their recitation of "specific primer" It is unclear how a specific primer comprising the recited sequence differs from a primer reciting that sequence.

Claim 24, line 11, claims 34-35, line 8, and claim 36, line 10, lack antecedent basis for the limitation "the foreign DNA".

Claim 24, line 11, claims 30 and 34--35, line 9, claim 36, line 11, claim 37, line 6 and claim 40, line 6, are indefinite in their recitation of "corresponding". It is unclear how the foreign DNA differs from SEQ ID NO:1. It is also unclear what the foreign DNA is within SEQ ID NO:1.

In claims 24, 26, 30, 34-37 and 39-42, it is unclear what portion of bases 1-234 of SEQ ID NO:8 are the 5' flanking region of MS-B2 and which are not, and it is not clear what portion

of bases 194-416 of SEQ ID NO:10 are the 3' flanking region of MS-B2 and which are not. If Applicant intended that those bases are the 5' and 3' flanking regions, then "from the ... comprised in" should be replaced with --of--.

In claim 30 is it not clear if "second specific primer or probe" in lines 7-8 refers to the "second PCR primer or probe" recites in lines 4-5 or if yet a different second primer or probe is intended.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
February 13, 2004

ANNE KUBELIK
PATENT EXAMINER